

## **Instructions for Submitting Confidential Business Information (CBI) and CBI-Deleted Information**

1. Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as confidential business information (CBI). Applicants must submit a written justification to support each claim.

2. "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.

3. Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."

4. The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.

5. Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI-deleted."

6. If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")

7. All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

## Animal and Plant Health Inspection Service

[Docket No. 85-406]

### Policy Statement on the Protection of Privileged or Confidential Business Information

This notice sets forth in full a document establishing the policy of the Animal and Plant Health Inspection Service for protecting certain privileged or confidential business information. This document reads as follows:

#### APHIS POLICY STATEMENT ON THE PROTECTION OF PRIVILEGED OR CONFIDENTIAL BUSINESS INFORMATION

##### I. Purpose

The purpose of this policy statement is to establish minimum requirements to control and protect documents received by the Animal and Plant Health Inspection Service (APHIS) that in its judgement contain privileged or confidential business information (CBI), as defined in section IV-E of this policy statement, concerning biotechnology and the Veterinary Biologics Program.

##### II. Policy

Title 7, Code of Federal Regulations, sections 1.1-1.16 contain the regulations of the United States Department of Agriculture (USDA) implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552). The FOIA generally provides that federal agencies must make available to the public all records not specifically exempt from disclosure. Section (b)(4) of the FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. 552(b)(4). This policy statement applies to the disclosure of CBI concerning biotechnology and the Veterinary Biologics Program. APHIS

will release such CBI only if disclosure is otherwise required by law, such as a specific statute or court order, by the source of the information, or as provided herein. In addition, APHIS employees shall take whatever measures are necessary to preclude unauthorized disclosure.

APHIS employees who make unauthorized disclosures of information classified as CBI can be subject to prosecution under the Trade Secrets Act, 18 U.S.C. 1905. Under this statute, a federal employee who discloses trade secrets and certain confidential data without authorization shall be fined up to \$1,000 and/or imprisoned for up to one year.

##### III. Applicable Statutes

- A. Freedom of Information Act Section (b)(4), 5 U.S.C. 552(b)(4)
- B. Trade Secrets Act, 18 U.S.C. 1905

##### IV. Definitions

###### A. Access

The ability and opportunity to gain knowledge of Confidential Business Information in any manner.

###### B. Administrator

The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any other official of the Animal and Plant Health Inspection Service to whom the Administrator has delegated authority to act.

###### C. Authorized User

An APHIS employee or other person whom the Administrator has certified as requiring access to Confidential Business Information.

###### D. Biotechnology

Any technique that uses living biological systems to make or modify products, to improve plants or animals,

or to develop microorganisms for specific uses.

##### E. Confidential Business Information (CBI)

Information that would be protected from disclosure under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)) will be classified as Confidential Business Information (CBI). This includes trade secrets and commercial or financial information found to be confidential.

##### 1. Trade Secrets

Documents containing trade secrets and which the person submitting asserts are trade secrets will be deemed CBI. "Trade secrets" means information relating to the production process. This includes production data, formulas, and processes, and quality control tests and data, as well as research methodology and data generated in the development of the production process. Such information must be (1) commercially valuable, (2) used in one's business and (3) maintained in secrecy.

##### 2. Commercial or Financial Information

Documents containing commercial or financial information will be deemed confidential if review establishes that substantial competitive harm would result from disclosure. Information such as safety data, efficacy or potency data, and environmental data may be such confidential information. Persons desiring protection for confidential information must submit a detailed statement containing facts to show that the person faces active competition in the area to which the information relates, and that substantial competitive harm would result from disclosure.

##### F. Destruction

Pulverization by a paper shredder, burning, or other approved method.

### *G. Information*

Knowledge that can be communicated by any means.

### *H. Secured Storage Area*

A room or equipment that is locked.

### *I. Staff Office*

A staff administering a particular program within the Animal and Plant Health Inspection Service.

### *J. Unique Identification Number*

The number permanently assigned to a document containing CBI when the document is logged in, and which enables the document to be tracked. Each document containing CBI will be assigned a separate number.

## **V. Identification of Confidential Business Information**

A. The applicable staff office shall review documents it receives to determine whether they contain Confidential Business Information.

B. The applicable staff office shall log in Confidential Business Information it receives, and shall assign unique identification numbers to allow for tracking.

C. A red cover sheet printed with the unique identification number shall be attached to the original and each copy of a CBI document.

D. In addition to the cover sheet, each page of each copy of a CBI document shall be stamped "CONFIDENTIAL."

E. A record of each copy of a CBI document and its disposition shall be maintained.

## **VI. Physical Security of Confidential Business Information**

### *A. Storage of CBI Documents*

1. CBI documents are to be stored in secured storage areas when not in use.

2. At the close of a business day, doors in secured work areas shall be locked, alarms activated if appropriate, and documents containing CBI in unsecured work areas shall be placed in secured storage.

### *B. Access To CBI Documents By Authorized Users*

1. The APHIS Administrator's office will maintain a list of persons authorized to have access to Confidential Business Information, and will furnish this list to staff office supervisors.

2. Persons will receive training on safeguarding CBI before obtaining authorized user status.

3. Authorized users shall obtain CBI documents through a person in each applicable staff office designated to be responsible for document control.

4. Requestors must present identification when obtaining CBI material from the applicable staff office. The requestor's name must appear on the authorized user list.

5. For each person on the authorized user list, a charge-out record will be kept. Requestors shall sign the record when receiving and returning CBI documents.

6. Person who terminates USDA employment will not receive exit clearance until all CBI documents that were charged out to the employee have been returned.

7. When an authorized user no longer requires access to CBI, the locks to which the person has had access must be changed.

### *C. Safeguards During Individual Use of CBI Documents*

1. All CBI documents must be handled by authorized personnel only.

2. Authorized users shall not in any manner disclose Confidential Business Information to unauthorized persons. Authorized users shall determine whether persons are authorized to have access to CBI before discussing CBI with them.

3. When unauthorized persons are present, CBI documents must be

covered, turned face down, removed from the area, or otherwise protected.

4. All persons are individually responsible for securing any CBI documents in their possession. When persons are reviewing or processing documents containing CBI, the documents are their responsibility until they are returned to the staff person responsible for document control. Persons handling CBI documents must secure them before leaving their work area.

5. Where working areas cannot provide privacy, private meeting areas will be provided for review of CBI documents.

6. Each person must safeguard keys to files, safes, rooms, etc. Keys to CBI files must be kept in a secured place. Lost keys or suspected breaches of security must be reported immediately to the person responsible for document control, so that changes can be immediately effected.

### *D. Meetings*

Precautions shall be taken so that unauthorized persons are not present at meetings where CBI is discussed.

## **VII. Copying and Destruction**

### *A. Photocopying*

1. Reproduction of documents containing Confidential Business Information shall be kept to a minimum.

2. A record of each copy of a CBI document and its disposition shall be maintained.

3. Bad copies shall be destroyed.

### *B. Destruction*

1. The person responsible for document control in each applicable staff office shall keep records of copies of CBI documents and their disposition.

2. The person responsible for document control shall perform any destruction of documents containing CBI.

3. When users of CBI documents have no further need for them, they shall return CBI documents to the staff office from which they obtained them. Unneeded copies will be destroyed in the staff office.

### **VIII. Transfer of Confidential Business Information**

#### **A. Within APHIS**

1. The applicable staff office shall assign unique identification numbers to CBI documents it receives. Copies to be sent to field offices or laboratories shall also be marked with the unique identification number.

2. All transfers of CBI materials within APHIS shall be recorded by the person responsible for document control in each applicable staff office.

3. All CBI documents transferred to field offices, laboratories, or other parts of APHIS must be logged in and out by a person responsible for document control in that office.

(a) Incoming CBI documents will be entered in the log, using the previously assigned unique identification number printed on the cover sheet.

The date of receipt will be recorded.

(b) Documents will then be filed in secured file cabinets.

4. Field offices and laboratories shall maintain security procedures equivalent to those described in this document. Field offices and laboratories shall be responsible for tracking and disposition of the CBI documents in their files.

#### **B. From APHIS to Other Parts of USDA, Other Federal Agencies, and Other Persons**

1. Persons from outside of APHIS must show that they need Confidential Business Information for a proper official purpose.

2. Persons from outside of APHIS must maintain security procedures equivalent to those of APHIS before they may receive Confidential Business Information.

3. The person submitting the CBI

will be notified of any requests by the public for disclosure and the scope of information to be disclosed, if any.

#### **C. Mail**

CBI documents shall be transmitted by registered mail, return receipt requested.

Effective date: September 18, 1985.

Dated: September 18, 1985.

**Bert W. Hawkins,**

*Administrator, Animal and Plant Health  
Inspection Service.*

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The following two pages are examples of CBI and CBI-deleted text of page III-8 of this Section.

HindII/BamHI fragment of Tn5 which contains NPT II (Rao and Rogers 1979). The NOS 3' polyadenylation and termination signal sequences were isolated and fused to NPT II (NEO) gene as previously described (White 1988). The chimeric NPT II gene was isolated as a BclII/BamHI fragment and cloned into BglIII site of pGV825 to produce pGC831.

DESCRIPTION OF RECIPIENT: The recipient organism, L. esculentum cv. Packard Clipper, is a common commercial cultivar and is a fresh market tomato. It is not widely grown in Maryland because of its susceptibility to CMV. Additional information on the biology of this tomato can be found in section 13h.

DESCRIPTION OF DONOR: CMV has been linked to plant disease in all temperate regions of the world. The virus has an extremely wide host range that includes cereals, forages, woody and herbaceous ornamentals, vegetables, and fruit crops. The RNA of CMV consists of four components of different size (approximate  $M_r$ : 1.01, 0.89, 0.68, and  $0.33 \times 10^6$ ). The three largest RNA's, which are distributed among three separate virion particles, carry all the information needed for successful infection. The genetic information for viral coat protein is carried on RNA 3 and on a coencapsidated subgenomic messenger RNA 4 (Kaper 1984). The viral coat protein assembles around the viral RNA to form the stable virion, which protects the nucleic acid from physical, chemical, or biochemical degradation. The coat proteins from different CMV strains usually have different amino acid sequences that reflect differences in nucleotide sequences of RNA 4 (Kaper 1984).

CMV strain PV 29 (also called strain 1) (American Type Culture Collection Catalogue, 14th Ed., 1988) was propagated as previously described (Lot et al. 1972) and dsRNA isolated as previously described (Diaz-Ruiz and Kaper 1978). Full-length ds cDNA copies of PV 29 CMV RNA 4 were prepared using synthetic oligonucleotide to prime RNA synthesis simultaneously from the 3' ends of both plus and minus strands of denatured ds RNA 4. The primer hybridizing to the plus strand contained an added ClaI recognition site at its 5' end to facilitate forced cloning into the plasmid vector. Additional details of this construct have been published (White 1988), and a reprint appears in appendix 1.

The promoter used in this study was derived from strawberry vein banding virus (SVBV), a caulimovirus (Shepherd 1979). The replication strategy of SVBV is thought to be analogous to the well-characterized cauliflower mosaic virus (CaMV). Upon infection of a cell with SVBV, two major RNA transcripts, designated 40S and 22S (based on their sedimentation coefficients), are produced during the replication of SVBV. These transcripts are analogous to the 35S and 19S CaMV RNAs (Hull and Covey 1983). The 40S SVBV promoter sequences have been characterized (further details in appendix 1). The 40S promoter was isolated as the HindIII/ClaI fragment extending from +9 to -343 with respect to the transcription start site mapped for the 40S RNA. The transcription termination and polyadenylation signal sequences were derived from the nopaline synthase (NOS) gene (Barker et al. 1983).

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The [40S promoter] and NOS termination signal sequences were blunt-end ligated to the cloned ] CBI CMV coat protein gene and inserted into pGV831 at the unique BamHI site. A map of the resulting plasmid pJLW180 is shown in figure 3. pJLW180 was introduced into the acceptor Ti plasmid pGV2260 by a single homologous recombination, using  $Sm^R$  gene of pJLW180 as a selectable marker for cointegration (see fig. 4 for map of cointegrate). The mobilization of pJLW180 from E. coli to Agrobacterium C58C1Rif<sup>R</sup> (pGV2260) was performed according to Van Haute et al. (1983). The structure of the T-region was confirmed by Southern blot hybridization.

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